Development and Validation of Chromatographic Methods for Estimation of Selected Antidiabetic Drugs

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By

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[February-2026]

DECLARATION

I, **Popaniya Hiralben Samatbhai**, Research scholar in the Department of Pharmacy declare that the work embodied in the Ph.D. thesis entitled, **"Development and Validation of Chromatographic Methods for Estimation of Selected Antidiabetic Drugs"** is my original and bonafide work carried out by me under the supervision of **Dr. Dineshkumar K. Dangar**, Asso. Professor, Dr. Subhash University for a period from *July-2022* to *February-2026* at Dr. Subhash University.

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ABSTRACT

Type II diabetes is treated with dapagliflozin, linagliptin and glimepiride. Dapagliflozin works by specifically blocking the sodium-glucose co-transporter-2 (SGLT-2) protein, while linagliptin belongs to the dipeptidyl peptidase-4 (DPP-4) inhibitor class and glimepiride is medium-to-long-acting sulfonylurea antidiabetic drug. It helps people with type II diabetes lower their blood sugar level.

The purpose of this study was to develop and validate an accurate, and stable reversed-phase liquid chromatographic (RP-HPLC) and LC-MS/MS analytical methods for determining the combined dosage form of dapagliflozin and linagliptin. According to International Conference on Harmonization (ICH), drug product and drug substances must undergo stability testing using approved stability-indicating liquid chromatography (HPLC) techniques developed through forced degradation research. Linagliptin and dapagliflozin subjected to forced degradation tests included acid and base hydrolysis, oxidation, heat and photo degradation.

The current study utilizes a quality by design approach to introduce a simple, robust, and liquid chromatography-mass spectroscopy analytical technique for quantifying glimepiride and linagliptin in synthetic mixture. The Box–Behnken Design (BBD) was used to examine effect of critical method parameters like heat block temperature, % organic solvent and flow rate, on critical quality attributes such as retention time and peak area.

Analytical techniques were established for the quantitative estimation of dapagliflozin, linagliptin and glimepiride using stability indicating RP-HPLC, LC-MS/MS and validated according to the ICH-Q2 (R1) guidelines. The suggested techniques were applied in pharmacokinetic research and also used for investigation of drugs in products.

Keywords: Dapagliflozin, Linagliptin, Glimepiride, Liquid Chromatography, Mass Spectroscopy, Validation, analytical Quality by Design.

Chapter 1
Introduction

One of the biggest health issue in the world is type II diabetes mellitus (T2DM), a chronic metabolic disease marked by elevated blood glucose level caused by either ineffective insulin secretion, ineffective insulin action or both [1]. The slow progression of T2DM and the increasing prevalence of both microvascular and macrovascular complications have led to the need to use combination pharmacotherapy to achieve ideal control in T2DM patients [2].

Recently, the use of Sodium Glucose Co-Transporter-2 inhibitors, Dipeptidyl Peptidase-4 inhibitors and sulfonylurea has gained considerable therapeutic value in terms of their mechanisms and safety profiles [3]. However, the formulation of the above active pharmaceutical ingredients in a combined dosage form has raised analytical issues due to differences in their polarity, solubility, concentration ratios and the possible decomposition products.

The assurance of pharmaceuticals quality necessitates the establishment and validation of selective, precise and stability-indicating analytical procedures capable of distinguishing active pharmaceutical ingredient from their degradation product. Such validated analytical techniques are essential to demonstrate the safety, efficacy and regulatory compliance of drug substance and finished formulation. Stability studies provide critical insights into degradation pathway and product performance under various environmental conditions. In this context, ICH Q1A(R2) guidelines mandate systemic stability evaluation to determine appropriate self-life and storage recommendation [4]. In addition, the analytical methods used in the process have to be validated as per the guidelines of the ICH Q2(R2) [5].

Because to its resilience and adaptability, RP-HPLC is commonly used as a routine quality monitoring tool [6]. In addition, it has been demonstrated that hyphenated chromatography techniques, such as liquid chromatography-tandem mass spectrometry (LC-MS/MS) are sensitive and specific, particularly in impurity profiling and trace level quantitation [7].

Current regulatory guidelines place significant emphasis on a scientific approach in analytical method development, and the ICH Q8 and ICH Q9 guidelines clearly support the importance of a pharmaceutical development approach based on risk assessment and quality risk management

principles [8,9]. More recently, ICH Q14 provides a framework for analytical procedure development and lifecycle management [10]. In this context, the aQbD approach offers a paradigm wherein the robustness and reliability of analytical techniques are enhanced through risk assessment, design of experiments and the identification of a method operable design region [11].

However, differences in polarity, concentration ratios and degradation attributes make it difficult to analyse these multi-component formulations. Although RP-HPLC methods have been extensively reported in the literature, many of these methods have not been comprehensively evaluated as stability-indicating methods. More advanced hyphenated tools like LC-MS/MS possess higher sensitivity and selectivity but have not been fully explored for the evaluation of these combinations. Moreover, the application of AQbD concepts in the development of chromatographic methods for these formulations has not been fully explored in the literature. Thus, there is a definite need for an integrated, stability-indicating, and AQbD-based LC-MS/MS analytical method for these antidiabetic combinations.

The main goal of this research is to develop systematic, robust, and regulatory-compliant analytical methodologies for specific combination of drug formulations.

Objective of the study

- To develop and validate stability indicating RP-HPLC method for simultaneous estimation of dapagliflozin and linagliptin in combined dosage form.
- To develop and validate LC-MS/MS method for simultaneous estimation of dapagliflozin and linagliptin in combined dosage form.
- To develop and validate LC-MS/MS method using AQbD approach for simultaneous estimation of glimepiride and linagliptin in synthetic mixture.

Although certain traditional RP-HPLC approaches have been established for specific combinations, overall stability-indicating approaches that include forced degradation studies and effective separation of degradation products have received insufficient attention. As a result, emphasis is placed on developing and utilising of effective stability-indicating technique that are capable of separating all degradation products under stressful circumstances.

Additionally, this work also seeks to establish highly sensitive and selective LC-MS/MS approach for the simultaneous quantification of these drug combinations dapagliflozin-linagliptin and

linagliptin-glimepiride. Since no LC-MS/MS methods optimised according to AQbD principles have been reported for these specific combinations, this attempt will utilise AQbD principles to create an analytical approach that is both risk –based and scientifically justifiable. Critical method parameters (CMPs), critical quality attributes (CQAs), design of experiments (DoE), the development of a method operable design region (MODR) and a robustness test are all part of this process.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, which cover parameters like specificity, linearity, accuracy, precision, sensitivity, robustness and stability will be used to validate all developed methods.

By designing a standardised stability-indicating and AQbD-based LC-MS/MS analytical approach for the chosen antidiabetic fixed-dose combinations, this thorough technique aims to be fill the current research gap.

Chapter 2

Literature Review Summary

Numerous analytical methods have been described in the table 2.1 and 2.2 for the determination of dapagliflozin, linagliptin, and glimepiride individually and in combination using RP-HPLC, LC-MS/MS and spectrophotometry techniques. However, variation in sensitivity, resilience, stability, and regulatory compliance have been observed.

Table 2.1 Summary report of analytical methods for Dapagliflozin and Linagliptin

Drug name → / **Analytical methods ↓**	**Dapagliflozin**	**Linagliptin**	**Dapagliflozin + Linagliptin**
UV spectroscopy	2	5	2
RP-HPLC	5	3	2
Stability Indicating RP-HPLC	2	2	-
LC-MS/MS	1	1	
HPTLC	1	-	1
UPLC	-	-	-

According to the literature study, several UV and RP-HPLC techniques have been design for the simultaneous and individual measurement of dapagliflozin and linagliptin [12]. However, the majority of techniques have only been used for regular assay analysis most of the methods have been restricted to routine analysis and have not undergone thorough evaluation for stability indicating reason.

No analytical approaches have been focused on the degradation aspects and LC-MS/MS approaches for simultaneous quantification of selected drugs in combined dosage forms. To, assess the selected antidiabetic combination analytically, a sensitive LC-MS/MS method and stability indicating RP-HPLC method must be developed.

Table 2.2 Summary report of analytical methods for Linagliptin and Glimepiride

Drug name → / **Analytical methods ↓**	**Linagliptin**	**Glimepiride**	**Linagliptin+ Glimepiride**
UV spectroscopy	5	2	2
RP-HPLC	3	4	2
Stability Indicating RP-HPLC	2	1	-
LC-MS/MS	1	1	-
HPTLC	-	-	1
UPLC	-	-	-

It is emphasizing that although a few conventional analytical techniques like UV spectroscopy and RP-HPLC are available for Linagliptin and Glimepiride, stability-indicating methods are less explored and this analytical strategy has been inadequately explored for selected combination [12,13]. There are limited LC-MS/MS techniques available for individual drug component, while no such method has been described for their combined dosage form. Furthermore, the literature does not report any LC-MS/MS technique established using AQbD framework for this selected combination. This demonstrates unequivocally a significant gap in the advancement of sophisticated analytical techniques for this combination.

Chapter 3

Materials and Methods

Materials and Reagents:

Table 3.1 lists the material and reagent used for the method development and validation, while table 3.2 lists the instruments used.

Table 3.1 lists the material and regents

Chemicals and Reagents	Grade	Company Name
Dapagliflozin	API	1.CTX Lifescience, India 2.Morepen Laboratories Ltd, Chandigarh, India.
Linagliptin		1. Pharmace Research Lab, Gujarat 2.Morepen Laboratories Ltd, Chandigarh, India.
Glimepiride		Intas Pharma, Ahemdabad
Methanol	HPLC	Fischer scientific India Pvt. Ltd., Mumbai, India
Water		
O-Phosphoric acid		
Potassium dihydrogen o-phosphate	AR	Rankem, Haryana, India
Hydrochloric acid		
Sodium Hydroxide		
Hydrogen Peroxide		
Formic Acid	HPLC	Fischer scientific India Pvt. Ltd., Mumbai, India
Acetonitrile		
Ammonium acetate		

Table 3.2 lists the instruments and Equipments

Instruments /Equipments	Model	Company name
Digital Weighing Balance	FA224	Precisa Pharma Pvt. Ltd., India
Digital Ultra Sonicator	CD-4820	Equipatron Bio-Technics, India
UV-Visible spectrophotometer	A116354	Shimadzu 1800,Japan.
HPLC system	LC10AD	Shimadzu, Japan
Digital pH meter	HKR01	Systonic, India
Digital Melting Point Apparatus	-	Abron exports
Auto-sampler	Shimadzu SIL-20AC	Shimadzu, Japan
Column oven	CTO-20AC	Shimadzu, Japan
Pump	LC-20ADvp	Shimadzu, Japan
Degasser	DGU-20A5R	Shimadzu, Japan
System Controller	CBM-20A SPD-M20A	Shimadzu, Japan
Operating Software	Lab Solution 5.99 SP2	-

For Dapagliflozin and Linagliptin

Method A- Development and validation of stability indicating RP-HPLC method for simultaneous estimation of dapagliflozin and linagliptin in combined dosage form.

Method B- Development and validation of LC-MS/MS method for simultaneous estimation of dapagliflozin and linagliptin in combined dosage form.

Method A- the final optimised condition for chromatography

Separation was achieved by using column Nova (C18, 250 mm x 4.6 mm, 5 µ). The optimized mobile phase was Buffer (Phosphate pH- 4 adjusted with OPA): Methanol (35:65 % v/v). The detection was carried out at 226 nm with flow rate of 1 mL/min, and. The chromatographic run time was 15 min and injection volume was 20 µL and. Dapagliflozin and linagliptin eluted at 8.27 min and 3.22 min respectively.

Method B- the final optimised condition for chromatography

An isocratic chromatographic approach was optimised using a Phenomenex Gemini C18 column (50 × 4.6 mm, 5 µm). The mobile phase consisted methanol (A) and 0.1% formic acid in water (B) in the ratio of 80:20 (% v/v) delivered at a flow rate of 0.5 mL/min with injection volume of 5 µL. The total analysis time was a 4.0-minutes, during which dapagliflozin and linagliptin eluted at approximately 1.8 and 0.8 minutes, respectively. The auto sampler and column were kept at 5 ± 3°C and 40 ± 0.3°C, respectively, to ensure the best possible separation and detection.

For Linagliptin and Glimepiride

Method C- Development and validation of LC-MS/MS method using AQbD approach for simultaneous estimation of glimepiride and linagliptin in synthetic mixture.

Method Optimization by aQbD Approach

1. Analytical Target Profile
1. Critical Quality Attributes
2. Critical Method Parameters
3. Risk Assessment
4. Design Experiment

Method C- the final optimised condition for chromatography

Method C- Linagliptin and Glimepiride final chromatographic condition were optimised using isocratic approach with X select Column containing 0.1% Formic acid: methanol (10:90 % v/v) at a flow rate of 0.5 mL/min and an injection volume of 5 µL. Linagliptin and Glimepiride eluted at approximately 2.7 and 1.6 minutes, respectively, out of 5.0-minute total run time. The auto sampler and column were kept at 5 ± 3°C and 40 ± 0.3°C, respectively, to ensure the best possible separation and detection.

Chapter 4

Results and Discussion

For Method A- Mobile phase consisting of different proportion of Buffer, Methanol and Water were tested. The Buffer (Dipotassium Hydrogen Phosphate) at pH 4 : Methanol (70:30 %v/v) at 1.0 mL/min flow rate, was shown to be superior to the other combination in the terms of peak shape, theoretical plate and asymmetry.

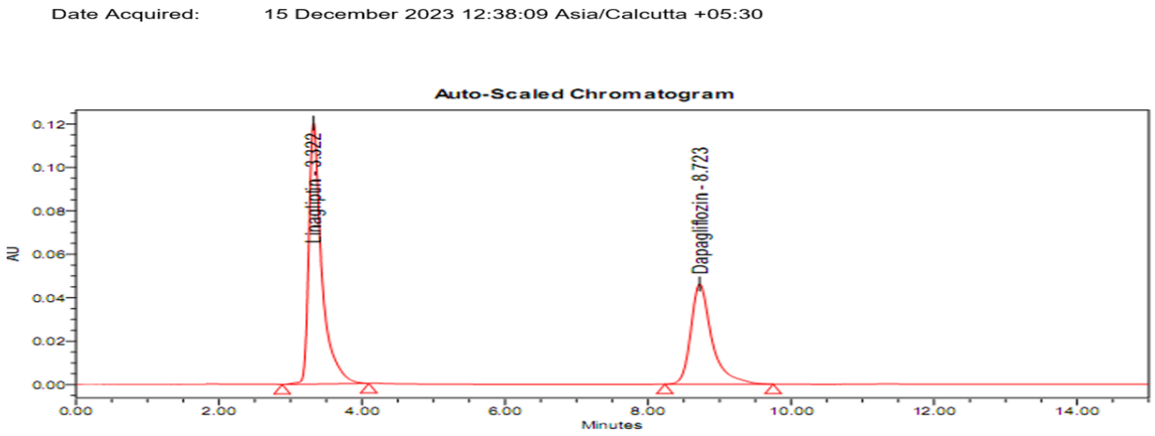


Figure 4.1 Chromatogram of DAPA (t_R: 8.723 min) and LINA (t_R: 3.322 min)

Table 4.1 Summary report of force degradation study for Dapagliflozin and Linagliptin

Sr. No	Degradation condition	Degradation condition for DAPA and LINA		% Degradation	
		Degradation condition Level	Duration	DAPA	LINA
1	Acid Degradation	0.1 N HCl	8 hr	0.02 %	0.39%
2		1 N HCl	12 hr	0.09 %	0.87 %
3		2 N HCl	24 hr	1.95 %	2.15 %
4		5 N HCl	1 hr	6.73 %	8.28 %

5	Alkali Degradation	0.1 N NaOH	8 hr	0.82 %	1.12 %
6		1 N NaOH	12 hr	1.14 %	1.96 %
7		2 N NaOH	24 hr	3.54 %	3.87 %
8		5 N NaOH	1 hr	26.78 %	29.65 %
9		5 N NaOH	30 min	11.11 %	13.97 %
10	Peroxide Degradation	3 % H_2O_2	6 hr	1.13 %	1.35 %
11		3 % H_2O_2	24 hr	1.78 %	2.14 %
12		10 % H_2O_2	24 hr	3.16 %	3.97 %
13		30 % H_2O_2	12 hr	14.87 %	16.42 %
14	Thermal Degradation	70 ºC	24 hr	11.4 %	10.33 %
15	Photolytic Degradation	UV Light (254 nm)	7 days	6.29 %	7.59 %

Table 4.2 Summary of result data for Dapagliflozin and Linagliptin (Method A)

Parameters	Dapagliflozin (DAPA)	Linagliptin (LINA)
Wavelength (nm)	226 nm	226 nm
Linearity (µg /mL)	8-80 µg /mL	4-40 µg /mL
Regression Equation (y= mx + c)	y = 22453x + 19014	y = 72643x + 13714
Regression coefficient	0.999	0.999
Slope (m)	22453	72643
Intercept (c)	19014	13714
LOD (µg /mL)	1.53 µg /mL	0.55 µg /mL
LOQ (µg /mL)	4.63 µg /mL	1.66 µg /mL
Accuracy	100.54 – 101.91 %	100.6-101.4 %
Precision (Intraday, Interday)	% RSD < 2	
Robustness	% RSD < 2	

For Method B

After conducting multiple experimental trials, optimal separation was obtained using a mobile phase composed of Methanol: 0.1% Formic acid (80:20 % v/v) and flow rate 0.5 mL/min. The detection process was performed in MRM by analyzing the m/z of 473.3→420.3 for linagliptin and 426.3→135.1 for dapagliflozin.

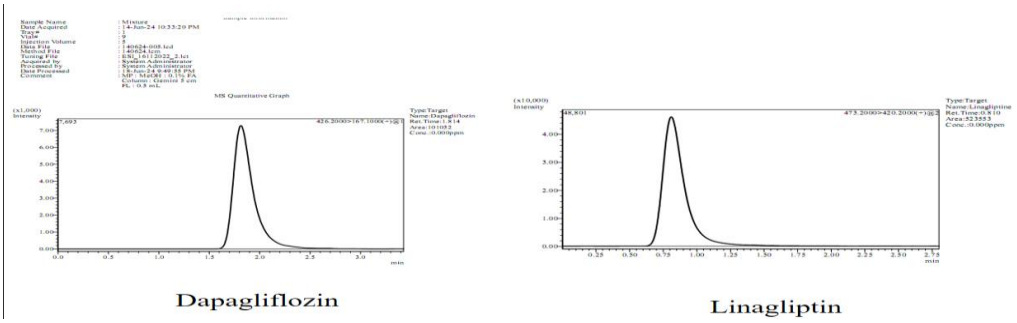
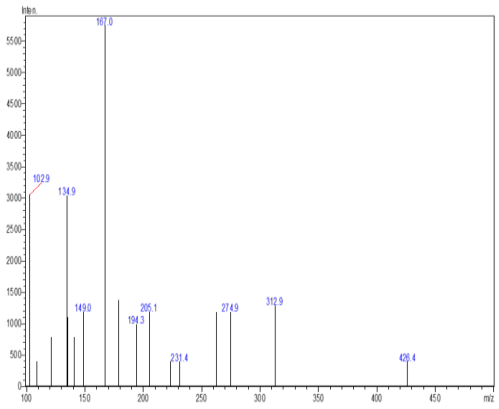
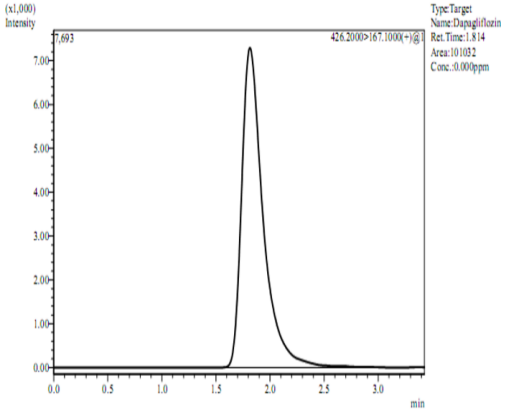


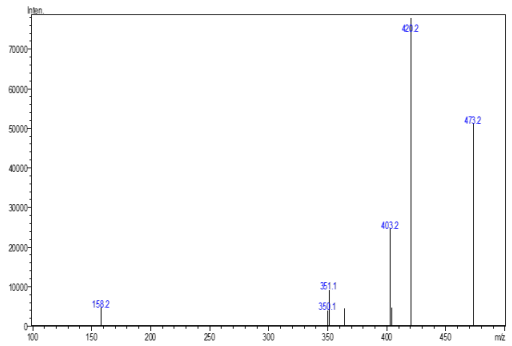
Figure 4.2 Chromatogram of dapagliflozin and linagliptin using Methanol: 0.1% Formic acid (80:20 % v/v)



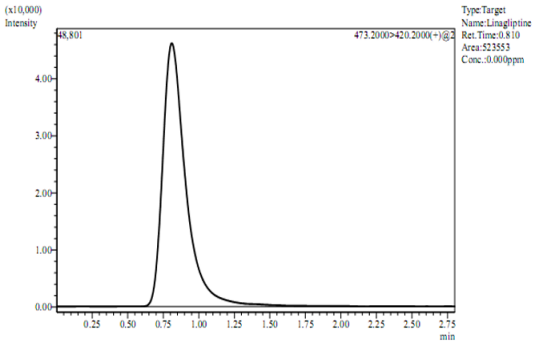
MS Spectra Dapagliflozin – Parent Ion



Chromatogram Dapagliflozin



MS Spectra Linagliptin – Parent Ion



Chromatogram Linagliptin

Figure 4.3 MRM spectra of dapagliflozin m/z 426.3>135.100 and linagliptin m/z 473.3>420.3

Table 4.3 Summary of result data for Dapagliflozin and Linagliptin (Method B)

Parameters	Dapagliflozin (DAPA)	Linagliptin (LINA)
Linearity (ng /mL)	5-500 ng /mL	10-1000 ng /mL
Regression Equation (y= mx + c)	y = 351.74x + 813.29	y = 1703.9x + 9764.9
Regression coefficient	0.9997	0.9993
Slope (m)	813.29	9764.9
Intercept (c)	351.74	1703.9

LOD (µg /mL)	0.31 ng /mL	0.72 ng /mL
LOQ (µg /mL)	0.93 ng /mL	2.18 ng /mL
Accuracy	99.9-101.8 %	99.9-101.8 %
Precision (Intraday, Interday)	% RSD < 2	
Robustness	% RSD < 2	

Linagliptin and Glimepiride

For method C- After conducting multiple experimental trials, optimal separation was obtained using a mobile phase composed of Methanol: 0.1% Formic acid (90:100 % v/v) and flow rate 0.5 mL/min. The detection process was performed in MRM by analyzing the m/z of 473.3→420.3 for linagliptin and 491.15→351.9 for glimepiride

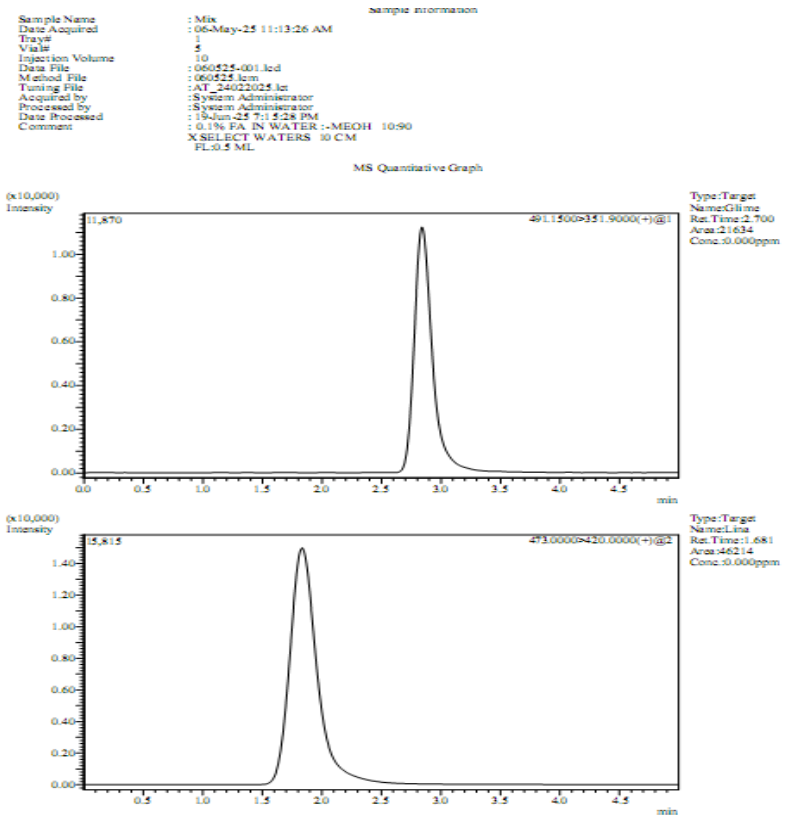


Figure 4.4 Chromatogram of GLIM (Rt-2.91) and LINA (Rt-1.81) in Methanol : 0.1% FA (90:10 v/v) Mobile Phase

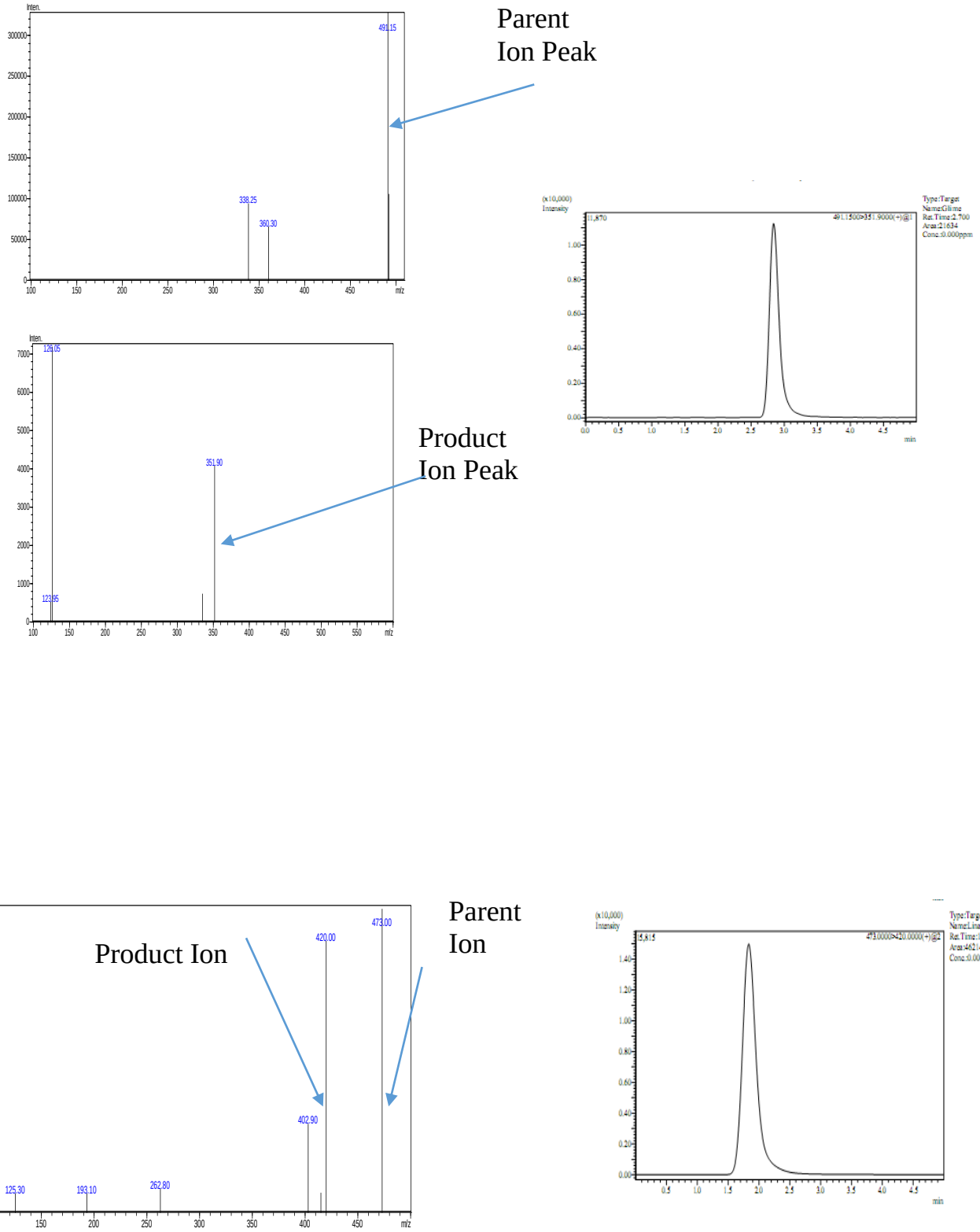


Figure 4.5 Mass spectra of Linagliptin m/z 473.00 > 420.00 and Glimepiride m/z 491.15 > 351.90

Table 4.4 Optimization of LC-MS/MS method using AQbD (Method C)

		X1	X2	X3	Y1	Y2	Y3	Y4
Standard exp. No.	**Run**	**Mobile phase (% v/v)**	**Flow Rate (ml/min)**	**Heat Block Temp. (ºC)**	**Retention time for LINA** (Min)	**Retention time for GLIM** (Min)	**Peak Area for LINA**	**Peak Area for GLIM**
6	1	82	0.6	450	1.514	2.826	187433	88672
1	2	90	0.4	400	2.279	3.553	298609	158100
13	3	90	0.5	450	1.83	2.843	244339	120995
14	4	90	0.5	450	1.826	2.847	254722	132275
8	5	98	0.6	450	1.716	2.161	85870	21348
4	6	90	0.6	500	1.531	2.382	222335	113616
5	7	82	0.4	450	2.253	4.228	245647	119424
11	8	98	0.5	400	2.097	2.592	99358	27774
7	9	98	0.4	450	2.604	3.24	136404	40566
15	10	90	0.5	450	1.826	2.85	257667	131533
3	11	90	0.4	500	2.267	3.554	303682	160569
2	12	90	0.6	400	1.534	2.385	201095	103023
10	13	82	0.5	500	1.805	3.381	208044	98142
16	14	90	0.5	450	1.834	2.851	265237	136656
12	15	98	0.5	500	2.003	2.592	103092	22263
9	16	82	0.5	400	1.804	3.38	195415	94009
17	17	90	0.5	450	1.828	2.849	260610	136120

Statistical analysis: Statistical evaluation within the Analytical Quality by Design (AQbD) framework was carried out using Design Expert ® (Version 13.0.0.1).

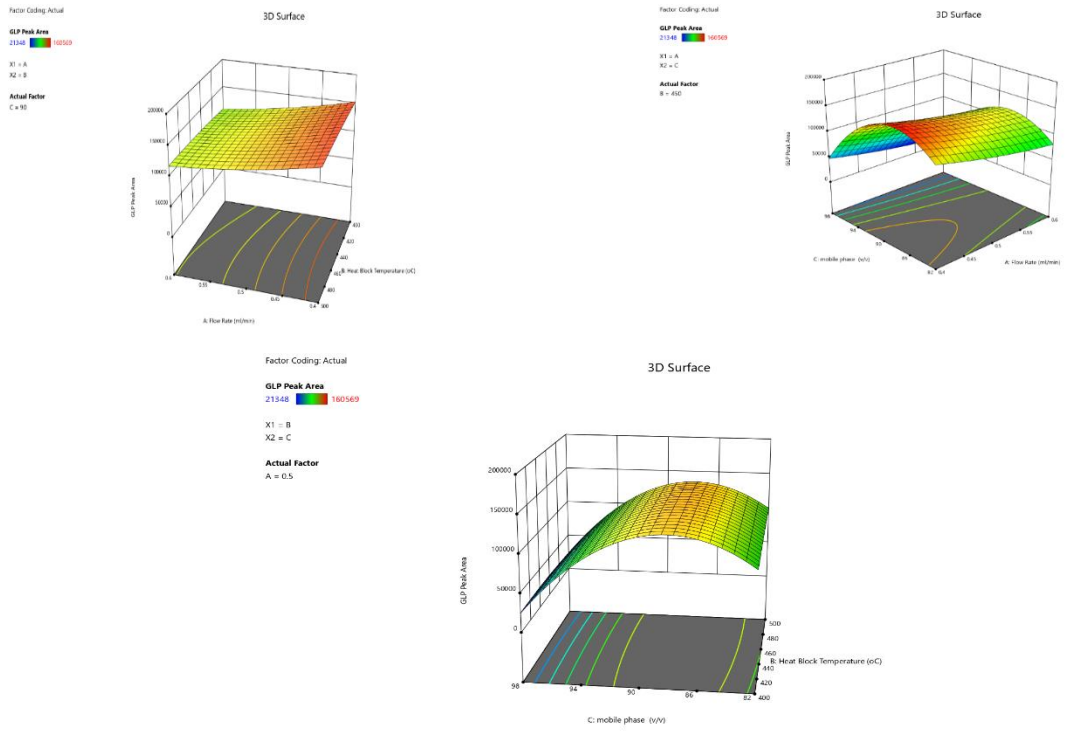


Figure 4.6 Effect of Mobile phase composition, Heat block temperature and flow rate on Peak Area GLIM

Table 4.5 Summary of results for Glimepiride and Linagliptin (Method C)

Parameters	**Glimepiride**	**Linagliptin**
Linearity • Range (ng/mL) • Linearity equation • Slope (s) • Intercept (c) • Correlation Coefficient	1-500 7413x + 40425 7413 40425 0.9985	2.5-1250 2884.7x + 36369 2884.7 36369 0.9986
Accuracy (% Recovery)	99.4-100 %	98.6-99.7 %
Precision • Intra-day precision • Inter-day precision	%RSD < 2 %RSD < 2	
LOD (ng/mL)	0.0272	0.33
LOQ (ng/mL)	0.083	0.1
Robustness (%RSD)	%RSD < 2	

Chapter 5

Conclusion

According to the analytical study, all proposed chromatographic techniques were determining to be robust, accurate, precise and economical.

For Dapagliflozin and Linagliptin

Method A:

Drug can be analysed using developed RP-HPLC technology when their degradant products are present. Hence, this chromatographic method is stability indicating in nature. It came out that developed RP-HPLC process was simple, precise, specific and accurate. % degradation range in force degradation was 5-20% which is follow here. % assay result for dapagliflozin and linagliptin 99.5 and 100.7 respectively. Therefore, this technique can be used for day to day evaluation of drugs in marketed formulation.

Method B:

A simple, sensitive and accurate LC-MS/MS technique was established and validated in compliance with ICH Q2 (R1) regulations. The process was successfully applied to quantification of Dapagliflozin and linagliptin and can be effectively utilized in pharmacokinetic study involving biological samples. % assay result of marketed formulation 99.73-99.60 % of dapagliflozin and linagliptin respectively.

For Linagliptin and Glimepiride

Method C:

In compliance with ICH Q2(R1) requirements, robust and sensitive LC-MS/MS technique was successfully developed and validated for the simultaneous quantification of glimepiride and linagliptin. The developed method demonstrates excellent performance characteristics and was found to be use in in pharmacokinetic investigation.

the Box- Behnken design, a three level design of experiments, was used to optimise critical chromatographic parameters. A multivariate analysis of some key process parameters, like 3 factors at 3 different level was carried out.

List of Paper Published

Research Paper Publication

1. Hiral S. Popaniya, Dinesh K. Dangar, Simultaneous Quantification of Dapagliflozin and Linagliptin in Pharmaceutical Formulation: A Stability-Indicating RP-HPLC Approach, International Journal of Biology, Pharmacy and Allied Science, 2026, 15(1): 416-428.

2. Hiral S. Popaniya, Dinesh K. Dangar, Eco-Friendly LC-MS/MS Method for Quantification of Dapagliflozin and Linagliptin in Combined Dosage Form: Development, Validation and AGREE Assessment, Indian Journal of Natural Sciences, 2025, 16(92): 101621-28.

Review Paper Publication

1. Hiral S. Popaniya, Dinesh K. Dangar, Chintankumar J. Tank. A Concise Review Based on Analytical Methods for Estimation of Dapagliflozin and Linagliptin in Pharmaceutical Dosage Form. Asian Journal of Pharmaceutical Analysis. 2024; 14(4):275-2. doi: 10.52711/2231-5675.2024.00049 Available on: https://ajpaonline.com/AbstractView.aspx?PID=2024-14-4-13

Research Paper Presented at Conference

1. Dual Drug Analysis: Stability Indicating RP HPLC Method for Dapagliflozin and Linagliptin in Combined Pharmaceutical Dosage Form was presented NOBCON 2024, 27-28 December,2024

Chapter 6

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